

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re P	atent Application of:) Group Art Unit: To Be Assigned	i
BEE e	t al.) Examiner: To Be Assigned	
Serial I	No.: 10/632,658) Atty. Docket No. GP103-03.DV	1
Filed:	August 1, 2003) Confirmation No.: To Be Assign	ed
For:	DETECTION OF <i>HIV-1 BY</i> NUCLEIC ACID AMPLIFICATION))	

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants bring to the Examiner's attention the references listed on the enclosed form PTO/SB/08 (two copies) for consideration in connection with the examination of the above-identified application. Copies of the cited references are enclosed herewith, except for the cited US patents and published applications.

In accordance with 37 C.F.R. § 1.97(b), this Information Disclosure Statement is being submitted within three months of the certified filing date of the instant application, and before the mailing date of a first Office Action on the merits.

IDS



Application Serial No.: 10/632,658 Atty. Docket No. GP103-03.DV1

Applicants respectfully request that the Examiner indicate consideration of the cited references by returning a copy of the enclosed form PTO/SB/08 with the Examiner's initials or other appropriate marks.

No fee is believed due in connection with this Information Disclosure Statement. If Applicants are mistaken, please charge the amount due to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

Respectfully Submitted,

Date: October 31, 2003

Christine A. Gritzmacher

Registration No. 40,627 Attorney for Applicants

GEN-PROBE INCORPORATED

Patent Department

10210 Genetic Center Drive

San Diego, California 92121

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Sheet 1

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 16

Complete if Known Application Number 10/632,658 Filing Date Aug. 1, 2003 First Named Inventor Gary G. Bee Art Unit To Be Assigned To Be Assigned **Examiner Name** Attorney Docket Number GP103-03.DV1

			U.S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (f known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	<u> </u>	US- 5,075,211	12/24/1991	Cosand et al.	
		^{US-} 5,185,439	02/09/1993	Arnold, Jr. et al.	
		US- 5,384,242	01/24/1995	Oakes	
		^{US-} 5,399,491	03/21/1995	Kacian et al.	
		^{US-} 5,427,930	06/27/1995	Birkenmeyer et al.	
		^{US-} 5,457,840	12/05/1995	Acevedo et al.	
		^{US-} 5,554,516	09/10/1996	Kacian et al.	
		^{US-} 5,569,582	10/29/1996	Tavernarakis et al.	
		^{US-} 5,582,989	12/10/1996	Caskey et al.	
		^{US-} 5,599,662	02/04/1997	Respess	
		^{US-} 5,602,240	02/11/1997	De Mesmaeker et al.	
		^{US-} 5,629,158	05/13/1997	Uhlen	
		^{US-} 5,629,413	05/13/1997	Peterson et al.	
		US- 5,658,737	08/19/1997	Nelson et al.	
		US- 5,684,147	11/04/1997	Agrawal et al.	
		US- 5,688,637	11/18/1997	Moncany et al.	
		^{US-} 5,693,535	12/02/1997	Draper et al.	
		^{US-} 5,700,922	12/23/1997	Cook	
,		^{US-} 5,702,365	01/06/1998	Ryder et al.	

		FORE	IGN PATENT DOCL	JMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	-6
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T°
•		DE 19850186 A1	05/25/2000	Roche Diagnost.		
		EP 0504278 B1	01/15/1997	Pharmacia		
		EP 0516540 B1	01/29/1997	CIS Bio Intl.		
		EP 1285971	02/26/2003	Tibotec Pharm.		
		WO 00/68436 A1	11/16/2000	Bosbach et al.		
		WO 93/07259 A1	04/15/1993	Sclerose-Foren.		

Examiner	Date	
Signature	Considered	
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Sheet 2

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	10/632,658	_			
Filing Date	Aug. 1, 2003	_			
First Named Inventor	Gary G. Bee				
Art Unit	To Be Assigned	_			
Examiner Name	To Be Assigned				
Attorney Docket Number	GP103-03.DV1	J			

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (* known) US- 5,710,029	01/20/1998	Ryder et al.	
		^{US-} 5,712,385	01/27/1998	McDonough et al.	
•		US- 5,739,308	04/14/1998	Kandimalia et al.	
		^{US-} 5,759,770	06/02/1998	Guertler et al.	
		^{US-} 5,759,773	06/02/1998	Tyagi et al.	
		^{US-} 5,763,171	06/09/1998	Stefano	
		US- 5,770,427	06/23/1998	Guertler et al.	
		^{US-} 5,786,177	07/28/1998	Moncany et al.	
		^{US-} 5,798,205	08/25/1998	Hauser et al.	
		^{US-} 5,827,656	10/27/1998	Nelson et al.	
		^{US-} 5,840,480	11/24/1998	Guertler et al.	
		^{US-} 5,856,088	01/05/1999	McDonough et al.	
		^{US-} 5,861,242	01/19/1999	Chee et al.	
		^{US-} 5,919,701	07/06/1999	Peterson et al.	
		us- 5,962,225	10/05/1999	Ramberg	
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		^{US-} 5,998,593	12/07/1999	Huff et al.	
		^{US-} 6,001,558	12/14/1999	Backus et al.	
		^{US-} 6,001,977	12/14/1999	Chang et al.	

Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code ³ "Number ⁴ "Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T
-		WO 99/07898 A1	02/18/1999	Akzo Nobel NV		
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Sheet 3

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known					
Application Number	10/632,658				
Filing Date	Aug. 1, 2003				
First Named Inventor	Gary G. Bee				
Art Unit	To Be Assigned				
Examiner Name	To Be Assigned				
Attorney Docket Number	GP103-03.DV1	J			

			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (f known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 6,007,983	12/28/1999	Dunn et al.	
	<u> </u>		01/11/2000	De Leys et al.	
	ļ	US- 6,013,484			
		^{US-} 6,110,678	08/29/2000	Weisburg et al.	
		^{US-} 6,162,631	12/19/2000	Hauser et al.	
		^{US-} 6,194,142	02/27/2001	Moncany et al.	
		^{US-} 6,232,455	05/15/2001	Kroeger et al.	
***		^{US-} 6.252,059	06/26/2001	McDonough et al.	
	\top	US- 6,265,152	07/24/2001	Dunn et al.	
		^{US-} 6,270,975	08/07/2001	Simon et al.	
		^{US-} 6,277,561	08/21/2001	Guertler et al.	
		^{US-} 6,280,952	08/28/2001	Weisburg et al.	
		^{US-} 6,294,338	09/25/2001	Nunomura	
		^{US-} 6,300,056	10/09/2001	Irvine et al.	
		^{US-} 6,303,293	10/16/2001	Patterson et al.	
	1	^{US-} 6,326,199	12/04/2001	Cook et al.	
	1	^{US-} 6,344,545	02/05/2002	Allaway et al.	
		^{US-} 6,372,427	04/16/2002	Kandimalla et al.	
		^{US-} 6,391,544	05/21/2002	Salituro et al.	
		^{US-} 6,399,294	06/04/2002	Charneau et al.	

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Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	١.
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Sheet 4

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complet if Known Application Number 10/632,658 Filing Date Aug. 1, 2003 First Named Inventor Gary G. Bee Art Unit To Be Assigned To Be Assigned **Examiner Name** Attorney Docket Number GP103-03.DV1

Examiner	Cito	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
Initials*	Cite No.1	Document Number	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant
1111111111	110.	Number-Kind Code ^{2 (F known)}		·	Figures Appear
		^{US-} 6,458,540	10/01/2002	Ramberg	
		^{US-} 6,492,110	12/10/2002	Hahn et al.	
		^{US-} 6,528,626	03/04/2003	Guertler et al.	
		^{US-} 6,531,137	03/11/2003	Guertler et al.	
		^{US-} 6,531,587	03/11/2003	Guertler et al.	
-		^{US-} 6,534,273	03/18/2003	Weisburg et al.	
		^{US-} 6,548,635	04/15/2003	Hauser et al.	
		^{US-} 6,551,824	04/22/2003	Guertler et al.	
		^{US-} 6,582,920	06/24/2003	Yang et al.	
		^{US-} 6,623,920	09/23/2003	Bee et al.	
		^{US-} 5,457,025	10/10/1995	Collins et al.	
		^{US-} 5,459,243	10/17/1995	Acevedo et al.	
		^{US-} 20020028459 A1	03/07/2002	Weisburg et al.	
		US- 20020068821 A1	06/06/2002	Gundling	
	 	us- 20020155428 A1	10/24/2002	Guertler et al.	
		us- 20020172939 A1	11/21/2002	Guertler et al.	
		^{US-} 20030003442 A1	01/02/2003	Guertler et al.	
	<u> </u>	^{US-} 20030003443 A1	01/02/2003	Guertler et al.	
		^{US-} 20030143535 A1	07/31/2003	Lyamichev et al.	

		FORE	IGN PATENT DOCU	MENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	
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Examiner Signature	Date Considered	

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of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Compl te if Kn wn Substitute for sym 1449/PTO **Application Number** 10/632,658 INFORMATION DISCLOSURE Filing Date Aug. 1, 2003 STATEMENT BY APPLICANT First Named Inventor Gary G. Bee Art Unit To Be Assigned (Use as many sheets as necessary) **Examiner Name** To Be Assigned Attorney Docket Number Sheet GP103-03.DV1 5 6 of

	·	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*			T²
		AGRAWAL et al., "Oligodeoxynucleoside phosphoramidates and phosphorothioates as inhibitors of human immunodeficiency virus", Proc. Natl. Acad. Sci., USA 85: 7079-7083 (1988).	
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		BILLYARD et al."Detection of HIV-1 RNA from Plasma Specimens Using Transcription Mediated Amplification", Clin. Chem. 41(11): 1684 (1995) (Abstract XP-000978913).	
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		BUSH et al."Detection of Human Immunodeficiency Virus Type 1 RNA in Plasma Samples", J.Clin. Microbiol. 30(2): 281-286 (1992).	
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		DEBYSER et al."Failure to Quantify Viral Load with Two of the Three Commercial Methods", Aids Res. Hum. Retroviruses 14(5): 453-459 (1998).	
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		GARDUNO et al. "Early detection of HIV-1 RNA from sero-conversion panels using Gen-Probe's", Clin Chem. 43(11): 2221 (1997) Abstract XP-000978914).	

Examiner	Date	
Signature	Considered	

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INF	ORMATION	I DIS	CLOSURE	Filing Date	Aug. 1, 2003	
STA	TEMENT E	BY A	PPLICANT	First Named Inventor	Gary G. Bee	
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Sheet	6	of	6	Attorney Docket Number	GP103-03.DV1	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		HEWLETT et al. "Co-amplification of multiple regions of the HIV-1 genome by the polymerase chain reaction: potential use", Oncogene, 4(9): 1149-1151 (1989).	
		LEPARC, "Nucleic Acid Testing for Screening Donor Blood", Infect. Med., 17(5): 320-333 (2000).	
		MATTHEWS et al., "Analytical Strategies for the Use of DNA Probes", Analytical Biochem., 169: 1-25 (1988).	
		O'SHEA et al., "Problems in the Interpretation of HIV-1 Viral Load Assays Using Commercial Reagents", J.Med. Virol., 61: 187-194 (2000).	
		OU et al., "DNA Amplification for Direct Detection of HIV-1 in DNA of Peripheral Blood Mononuclear Cells", Science, 239: 295-297 (1988).	
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		VAN GEMEN et al., "The One-tube Quantitative HIV-1 RNA NASBA: Precision, Accuracy", PCR Methods & Applns., 4:S177-S184 (1995) Cold Spring Harbor Laboratory.	
		YANG et al., "Detection of HIV-1 RNA Subtypes with Transcription-Mediated Amplification", Abstracts of the General Meeting of the ASM, 97:538 (1997) (Abstract) XP-000980335.	
-		ZIMMERMANN et al., "Rapid Nonradioactive Detectioof HIV-1 RNA from a Single-Cell Equivalent", Biotechniques 15(5): 806, 808 (1993).	

Examiner	Date	
Signature	Considered	

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